



Jillian Skinner
Minister for Health

MEDIA RELEASE

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NEXT GENERATION OF MEDICAL INNOVATORS

Health Minister Jillian Skinner tonight congratulated 12 outstanding medical researchers as they graduated from the 2015 Medical Device Commercialisation Training Program.

Presenting certificates at a ceremony at ATP Innovations, Eveleigh, Mrs Skinner said the graduates represent the next generation of medical innovators.

"These entrepreneurial graduates come from medical, biomedical engineering, mechatronics and biological science research backgrounds," Mrs Skinner said.

"Their research includes a templating system to develop patient-customised implants, a new method of heart valve repair and a home diagnostics kit for medical testing."

The Medical Device Commercialisation Training Program (MDCTP) was set up following a review of the first round of the NSW Government's Medical Devices Fund. It aims to address a gap between the skill base in the development of medical device research and the skills required to commercialise emerging innovative technologies.

As part of the 2015 program, ATP Innovations provided a three-month intensive training course aimed at early-to-mid-career, post-doctoral and other researchers.

Mrs Skinner awarded four members of the graduating class with scholarships to further develop their research:

- **Professor Stephanie Watson, Kleer-i** - \$50,000 in seed funding for the Kleer-i patch, a sutureless wound sealing device for cataract surgery;
- **Dr David Yeo, Royal Prince Alfred Hospital** - \$25,000 in seed funding for Pivot Sphincterotome, a procedure for the management of bile duct pathology;
- **Dr Dharmica Mistry, BCAL Diagnostics Pty Ltd** - \$10,000 international engagement scholarship for higher accuracy breast imaging and screening tests;
- **Dr Robert Gorkin, University of Wollongong** - \$10,000 international engagement scholarship for new condoms utilising an advanced hydrogel material with anti-STI agents.

"It takes a breadth of skills to get an innovative medical research concept off the ground and our graduating researchers are now equipped with the skills required to bring their fantastic ideas into the marketplace," Mrs Skinner said.

The first group of MDCTP trainees graduated in late 2014.

For more information visit: <http://www.health.nsw.gov.au/ohmr/pages/default.aspx>

Medical Device Commercialisation Training Program 2015: Graduates

CANDIDATE	INSTITUTION	PROJECT
Aiden O'Loughlin	University of Western Sydney	<p>Stabilizer: One in three people in Australia die of cardiovascular disease. The underlying process causing the majority of these deaths is atherosclerosis. Atherosclerosis is a disease where fatty material is deposited in sections of the wall of the artery. Deaths occur when local atherosclerotic lesions rupture, stimulating clot formation, leading to occlusion of the artery. These lesions are termed 'vulnerable plaques'. Both heart attacks and strokes can be caused by vulnerable plaques rupturing. Recent research has shown that vulnerable plaques can be identified prior to their rupture. The Stabilizer device provides treatment that will prevent future heart attacks and strokes with the development of a locally applied treatment to stabilise these plaques.</p>
Annabelle Chan	University of Sydney	<p>Rapid Templating System: The rise in rapid prototyping technologies has presented a unique opportunity for the creation of custom made implants. However, the logistical shift from generic high volume production systems to individually customised implants prevents its widespread usage. The Rapid Templating System aims to form patient specific</p>

		<p>implants quickly and effectively. The system involves the production of a 3D-printed guided mould, based on patient scans, to shape terminally sterilised generic materials into patient-customised implants. The generation of custom implants within packaged materials allow implants to be immediately ready for use, avoiding treatment delays due to sterilisation post production. This approach has the capacity to significantly reduce inventory costs for medical device companies, as abundant implant-size ranges are no longer required to accommodate all patient cases. Further developments in regenerative medicine may allow further customisation material properties, allowing the implant to be patient specific anatomically as well as a biomechanically.</p>
David Yeo	Royal Prince Alfred Hospital	<p>Pivot Sphincterotome: Endoscopic retrograde cholangiopancreatography (ERCP) is an endoscopic procedure that allows access into the biliary system and has revolutionised the management of bile duct pathology. However, it is a notoriously difficult procedure to learn and even in experienced hands, this procedure is associated with complications including pancreatitis, bleeding, perforation and in rare cases, death. Cannulation of the bile duct remains the most challenging step of the procedure even with current sphincterotome technology. The Pivot Sphincterotome</p>

		<p>has been developed to facilitate easier, faster and ultimately safer biliary access. The ERCP sphincterotome US market alone is worth approximately \$USD150 million and with an increasingly elderly population requiring less invasive procedures, it is expected to increase. Developed by an ERCP practitioner, the Pivot Sphincterotome aims to accommodate the shortcomings of current technology making the ERCP experience more user-friendly, efficient and safe.</p>
Dharmica Mistry	BCAL Diagnostics Pty Ltd (BCAL Dx)	<p>BCAL Diagnostics: To develop and commercialise a novel universal screening test for the detection of breast cancer that is highly accurate, safe, cost effective, and available to all women regardless of age, race and geographic location. Breast cancer is the most common cancer amongst women, therefore, the effectiveness of the screening and diagnosis technology used is a high priority. The current model relies on a woman being physically present at a clinic for breast imaging which is not always convenient. While the present technologies are currently state of the art, there is a high cost involved. There are also well known performance limitations that result in only a small subset of women who are actually eligible for screening. BCAL Diagnostics aims to shift the paradigm in breast cancer screening and diagnosis by introducing a blood test for detection of the</p>

		<p>disease. The implication of such a technology could revolutionise the way breast cancer is managed by allowing a blood sample to be taken remote from the site of analysis. This technology will allow access to more women, anywhere in the world, who could provide a blood sample, at a time and place convenient to them. Such a test would fit into a woman's routine health regime and be incorporated into their personal lifestyle. In addition, with such high levels of accuracy, this technology would provide greater peace of mind between annual checks. The BCAL Diagnostics technology could utilise a single blood test on multiple levels for disease prevention, diagnostic mass screening and post-intervention.</p>
James Otton	Liverpool Hospital	<p>SeCure Beating Heart Repair: Mitral regurgitation is a condition caused by a leaking heart valve and affects more than four million individuals in the USA. The standard method of fixing valves is with open heart surgery, a complex operation performed on cardiopulmonary bypass. The operation is expensive, and recovery time from the operation is measured in weeks or months. The SeCure Beating mitral heart repair device enables heart valve repair while the heart is still beating, with no need for bypass or long anaesthesia time or surgical scars. Patients can recover in hours or days and the cost of surgery can be dramatically reduced. The heart repair can be repeated if necessary</p>

		and conventional surgery can also be performed at a later date. With the new technology many patients who have been deemed unfit for surgery could be given lifesaving treatment.
Robert Gorkin	University of Wollongong	Geldom: Backed by experts at the University of Wollongong and Swinburne University of Technology, Geldom is helping make condoms more wearable by replacing latex with better feeling materials called tough hydrogels. These tough hydrogels are superior to latex and can improve the experience by offering more tissue like sensation. They also have other revolutionary benefits – no bad odours or tastes, no latex allergies, inherent self-lubrication, and can even be embedded with anti-sexually transmissible infections agents or stimulants. These new options have the potential to dramatically increase condom use. The impact – not only redefining what safe sex should feel like – but the added social benefits of improved family planning and disease prevention. This work is geared towards disrupting the \$6 billion condom industry desperate for innovation. This patent pending work has been supported by the Bill & Melinda Gates Foundation and has featured on ABC's Catalyst.
Josef Goding	University of New South Wales	CardioFlex: is the next generation of cardiac pacemaker leads. Conventional pacemaker leads are comprised of a long, coiled metal wire

		<p>running from the neurostimulator to the electrode implanted in the heart. These conventional leads are prone to infection, dislodgement and mechanical failure. They are also incompatible with MRI because they act as antenna and generate unsafe amounts of heat in the body under MRI. CardioFlex leads do not use metal wires but are instead fabricated from conductive elastomers, a novel material being developed at UNSW. Conductive elastomers allow the CardioFlex lead to be soft, flexible and totally MRI compatible. This means recipients are less likely to require a surgical lead extraction and they do not need to worry about their pacemaker interfering with ongoing or future medical treatments. Other applications of conductive elastomers being investigated include flexible electrode arrays and nerve cuffs for neural interfacing.</p>
Sandra Ast	AusSI Systems	<p>AusSI Systems: This product allows for simple medical testing remotely from home. The home diagnostics kit consists of a small device attachable to a smartphone and together with an app, it allows for the analysis of the same urine dipsticks that are commonly used in the GP's office. The medical results can then be shared with the GP online instead of going to the doctor, when unwell or busy. This will assist in a comprehensive assessment of the patient's health problem currently not possible via online consultations. This</p>

		<p>smartphone diagnostics device also features recording of the test results over time opening up numerous additional applications, ranging from personalised healthcare to new testing methods for diseases.</p> <p>As the healthcare sector is moving towards a digital platform, these internet connected devices will be essential in the generation of digital medical records as well as the successful implementation of online medical services.</p>
Sean Pollock	Respiratory Innovations	<p>Breathe Well is an interactive medical device that allows breast cancer patients to help improve their own cancer treatment, simply by breathing. In breast cancer radiation therapy, nearby healthy tissues like the heart and lungs are at risk of receiving unnecessary, and potentially fatal, radiation damage. Breathe Well shows patients how to hold their breath to put as much distance possible between the heart and radiation beam to achieve the most accurate breast radiation treatment possible.</p>
Stephanie Watson	Save Sight Institute	<p>Kleer-i: One in twenty cataract surgery wounds leak, causing infection and blindness to occur. Sutures cause scarring, are time-consuming to apply, require great skill, and distort vision. In addition to this, patients have poor compliance with postoperative eye drops. Cataract surgery is the most common operation and has the longest waiting list in NSW. Eye surgery costs are</p>

		<p>rising as the population ages. Kleer-i is a next-generation “patch”, bonded over an eye wound by a low-powered laser. It falls off once the wound heals. Surgeons will use Kleer-i to rapidly seal eye wounds without sutures, while simultaneously delivering drugs. Kleer-i will save 25% to 40% of operating time and promote faster wound healing, reducing vision loss from scarring, distortion and infection.</p> <p>Kleer-i is unique in combining drug delivery with suture-less wound closure. It avoids the toxic side-effects and high failure rates associated with existing therapies: sutures, histoacryl glue and fibrin sealant.</p>
Stephen Bradford	CSIRO/Garvan Institute of Medical Research	<p>MethylC&Me: Obesity is a growing global health problem with direct costs estimated at \$21 billion annually (Australian Diabetes, Obesity and Lifestyle Study). Current therapeutic and policy intervention is not working. Evidence suggests that early directed intervention for individuals with a predisposition to obesity and related co-morbidities is more effective at maintaining long term positive health outcomes. This technology measures the levels of specific modifications to a person's DNA (DNA methylation marks) that are associated with current or future health status. The core IP is in panels of such DNA methylation biomarkers that could be used to identify an individual's risk and likely trajectory for obesity and Type 2 diabetes mellitus. This would help direct</p>

		clinicians, such as endocrinologists and dietitians, in the clinical management of patients and identify at risk people early – reducing the health burden of chronic disease.
Yang Chen	Woolcock Institute	<p>Scintilla Electrostatic Inhaler: Metered dose inhalers (MDI) are a commonly used device to deliver aerosolised medications for the treatment of pulmonary diseases. The emitted aerosols from MDI contain millions of fine particles that carry intrinsic charge that is imparted on them during the atomisation phase. These static charges can cause variations in particle aerosolisation and dosage. Moreover, the MDI requires manual actuation force to operate and its efficacy relies on patient's co-ordination between actuation and inhalation, which can be difficult for elderly patients with chronic obstructive pulmonary diseases (COPD). The Electrostatic Metered dose inhaler (EMDI) is a novel electrostatic metered dose inhaler, which utilises electronic force and electrostatic charges to generate inhalable aerosol. It will reduce the need of excipients in the drug formulation to help with the aerosolisation process, and also minimise the difficulties that can occur when using conventional MDIs. EMDI can provide more efficient treatment to people with respiratory diseases, especially for the 65 million patients who currently suffer from COPD around the world.</p>